AUG 2 3 2001

STD Manufacturing, Inc., Confidential – Trade Secret

Special 510(k) Pre-Market Notification

510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92

The assigned 510(k) number is: K012362

Submitted by: **Stephen M. Palumbo**
Director of Regulatory Affairs
STD Manufacturing, Inc.
1063 Turnpike Street
Stoughton, MA 02072
Telephone #:(781) 828-4400 Facsimile #:(781) 344-5895

Date Prepared: 17 July 2001

Establishment Registration Number: STD Manufacturing, Inc. is located at 1063 Turnpike Street, Box 420, Stoughton, MA 02072. We are registered with the Food and Drug Administration as Establishment Number **1222928.**

Classification Name: Staple, Implantable (GDW)
General and Plastic Surgery
21 CFR § 878.4750 (1999)

Common/Usual Name: Stapler/ Clip Applier, with Implantable Staple

Proprietary Name: Vascular Closure Device

Indication for Use: The Vascular Closure Device indications for use are to approximate vascular, small tubular structures, and general tissue for achieving hemostatic closure of wound or puncture site to aid healing in minimally invasive or open procedures for full body applications.

Device Description: See Product Description Section on pages 17 and 18.

K012362 (p.2 of 2)

Special 510(k) Pre-Market Notification

510(k) Summary (Cont.)

Substantial Equivalence Claim: The Vascular Closure Device is substantially equivalent to the Vascular Closure Device cleared under ***K#003169***

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 3 2001

Mr. Stephen M. Palumbo
Director, Regulatory Affairs
STD Manufacturing, Inc.
1063 Turnpike Street
P.O. Box 420
Stoughton, Massachusets 02072

Re: K012362
Trade/Device Name: Vascular Closure Device
Regulation Number: 878.4750
Regulatory Class: II
Product Code: GDW
Dated: July 17, 2001
Received: July 25, 2001

Dear Mr. Palumbo:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Special 510(k) Pre-Market Notification

510(k) Number (if known): K012362

Device Name: **Vascular Closure Device**

Indications for Use:

The Vascular Closure Device (VCD) Indications for use is to approximate vascular, small tubular structures, and general tissue for achieving hemostatic closure of wound or puncture sites to aid healing in minimally invasive or open procedures for full body applications.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109

Over-The Counter Use _____

(Optional Format 1-2-96)

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012362